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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,266	11/28/2005	Matthew Freeman	MEWE-022	7351
24353	7590	12/11/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			SHEN, BIN	
			ART UNIT	PAPER NUMBER
			1657	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/533,266		FREEMAN, MATTHEW	
	<b>Examiner</b>		<b>Art Unit</b>	
	Bin Shen		1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 23-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>          </u>  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1657

#### **DETAILED ACTION**

The IDS received 4/28/2005, the preliminary amendment received 4/28/2005, 11/28/2005 have been entered.

#### ***Election***

Applicant's election of Group I, claims 1-22, in the reply filed on 10/19/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 23-36 are nonelected and thus are withdrawn from further consideration.

Claims 1-22 are presented for examination on the merits.

#### ***Specification***

1. The abstract of the disclosure is objected to because the abstract must be a single paragraph. Correction is required. See MPEP § 608.01(b). A new abstract on a separate page is required to replace the current abstract, which is the first page of the WO document of the application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1657

2. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is incomplete because it lacks a correlating step to accomplish the preamble of the claim.

Claims 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is claimed due to improper use of Tables (1 and 2). Correction is needed to clearly define the exact sequences being claimed.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Urban et al. (Cell 2001;107:173-182) in view of Blackman et al. (JBC 1998;273(36):23398-23409).

Art Unit: 1657

Urban teaches a method of detecting proteolytic activity of *Drosophila* serine proteases that cleave at a corresponding site in the TMD of Spitz (page 173, right column, 3<sup>rd</sup> full paragraph), and the implication of a bacterial Rhomboid in intercellular signaling suggesting that intramembrane proteolysis by Rhomboids may be a widespread signal activating strategy (page 174, left column, lines 8-12).

Urban does not teach a method for identifying a compound which inhibits infectivity of a protozoan pathogen, a substrate polypeptide comprising TMD of the *Drosophila* Spitz sequence, or the substrate polypeptide is Ama-1 or CTRP, the detectable label is GFP, the determination of the ability of the test compound to inhibit the invasiveness of a protozoan pathogen.

Blackman teaches an isolated parasite (*Plasmodium*) proteolytic enzyme (expressed in a host cell from heterogeneous nucleic acid-page 23399, right column, 4<sup>th</sup> full paragraph) abstract and page 23403, right column, lines 5-7), a method to detect the invasiveness of a protozoan pathogen (page 23400, right column, 2-3<sup>rd</sup> full paragraph), the involvement of an obligate intracellular apicomplexan parasite protease in invasion of human malaria (page 23398, left column, 1<sup>st</sup> paragraph, and right column end of 1<sup>st</sup> full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Urban by using the substrate polypeptide comprising the TMD of the Rhomboid polypeptide cleavage site from Spitz sequence to identify a compound which inhibits infectivity of a protozoan pathogen because Blackman teaches that parasite proteolytic enzymes play an essential role in invasion (abstract lines 3-4). One would have been motivated to make the modification because Urban

Art Unit: 1657

specifically described a method of detecting proteolytic activity of Rhomboid polypeptide and Blackman teaches parasite proteases involved in invasion are attractive potential targets for new rational approaches to antimalarial chemotherapy (page 23398, right column, end of 1<sup>st</sup> full paragraph), and would reasonably have expected success in view of Urban's teaching that Rhomboid polypeptide is a polytopic membrane protein that is a member of a large protein family with homologs in many species (page 180, end of left column) if not all organisms. The adjustment of particular conventional working conditions (e.g., choice of substrate polypeptide and proteolytic cleavage site, labeling substrate with GFP) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her. Isolating, synthesizing, modifying and formulating test compound for its pharmaceutical use are all necessary steps in developing antimalarial drug and is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### **Conclusion**

4. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such

Art Unit: 1657

papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Art Unit: 1657

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

*R. Gitomer*

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200

*B Shen*

Art Unit 1657